Docket No.: PF-0309-3 DIV

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By: _____ Printed: MARGARET M HANSON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Au-Young et al.

Title: TWO NEW HUMAN DNAJ-LIKE PROTEINS

Serial No.:	09/501,714	Filing Date:	February 10, 2000
Examiner:	Slobodyansky, E.	Group Art Unit:	1652

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AP
8/15/02

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REPLY BRIEF

Sir:

In response to the Examiner's Answer mailed May 31, 2002, herewith are three copies of Appellants' Reply Brief on Appeal. This Reply Brief addresses the issues raised in the Examiner's Answer.

I. Introduction

In the Examiner's Answer, the Patent Examiner withdrew the rejections of:

1) claims 54-56 and 66 under 35 U.S.C. § 112, first paragraph (Issue 2, enablement);

2) claims 45 and 52 under 35 U.S.C. § 102(a) over the EST taught by Hillier et al.;

3) claims 45 and 52 under 35 U.S.C. § 102(a) over any of the two ESTs taught by Hillier et al.;

4) claims 45 and 52 under 35 U.S.C. § 102(b) over the EST taught by Weissenbach; and

5) claims 54 and 66 under 35 U.S.C. § 103(a) over the EST taught by Weissenbach.

In addition, the Examiner maintained the rejections of (a) claims 45, 47-49, 52, 54-56 and 66-68 under 35 U.S.C. § 112, first paragraph on the grounds that the claimed isolated polynucleotide variants encoding a polypeptide selected from the group consisting of, *inter alia*, "a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or SEQ ID NO:3, and a polynucleotide complementary thereto" or "a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 or SEQ ID NO:4" allegedly do not meet the written description requirement under 35 U.S.C. § 112, first paragraph (Examiner's Answer, pp. 5-8 and 10-12), and (b) claims 54 and 66 under 35 U.S.C. § 103(a), as allegedly obvious in view of any of the Hillier et al. sequences (Examiner's Answer, pp. 13-14).

II. WRITTEN DESCRIPTION REJECTION

Nowhere in the Reply Brief does the Examiner offer any evidence that one of ordinary skill in the art would not have understood, from the disclosure in the specification, along with "[w]hat is conventional or well known to one of ordinary skill in the art," that Appellants were in possession of the claimed polynucleotide variants. The Examiner instead merely repeats that "[w]hile one skilled in the art is enabled to detect such naturally-occurring sequences, it is impossible to visualize them without knowing the correlation between SEQ ID NO:2 or SEQ ID NO:4 and mutational sites." (Examiner's Answer, page 11.)

The Examiner's position is clearly contrary to the USPTO's own written description guidelines ("Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001), which provide that:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics[42] which provide evidence that applicant was in possession of the claimed invention,[43] i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[44] **What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.[45] If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[46]** (emphasis added)

Here, there simply is no requirement that the claims recite particular variant polynucleotide sequences because the claims already provide sufficient structural definition of the claimed subject matter. That is, the claimed polynucleotide variants are defined in terms of SEQ ID NO:2 or SEQ ID NO:4 ("An isolated polynucleotide comprising a sequence selected from the group consisting of: a) a polynucleotide sequence of SEQ ID NO:2 or SEQ ID NO:4, b) a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 or SEQ ID NO:4..."; claim 52) or SEQ ID NO:1 or SEQ ID NO:3 ("An isolated polynucleotide encoding a polypeptide selected from the group consisting of: a) an amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3, and b) a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or SEQ ID NO:3, and a polynucleotide complementary thereto"; claim 45). Because the claimed polynucleotide variants are defined in terms of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, the precise chemical structure of every polynucleotide variant within the scope of the claims can be discerned. The Examiner's position is nothing more than a misguided attempt to require Appellants to unduly limit the scope of their claimed invention.

III. Prior Art Rejection

Although the Examiner continues to insist that the methods of claims 54 and 66 are obvious in view of the Hillier et al. sequences (accession N933160, accession W63690 or accession AA020916), the burden to make the required *prima facie* case of obviousness that is required to apply a rejection under 35 U.S.C. § 103 to claims 54 and 66 has not been met. The requirements for rejection of claims under 35 U.S.C. § 103 are set forth in MPEP 706.02(j):

> 35 U.S.C. authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:
>
> (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
>
> (B) the difference or differences in the claim over the applied reference(s),
>
> (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
>
> (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

Rather than provide the information necessary to meet the requirements for rejection of claims under 35 U.S.C. § 103, the Examiner has instead substituted her personal opinion that "the whole reason for creating databases containing partial nucleotide sequences is to use them for detecting full length sequences" (Examiner's Answer at p. 14).

Appellants assert that the Examiner has not presented any reasons why the Hillier et al. sequences would have motivated one of ordinary skill in the art at the time the invention was made to use any of the sequences disclosed in Hillier et al. in "***[a] method for detecting a target polynucleotide in a sample,*** said target polynucleotide ***having a sequence of a polynucleotide of claim 52***" or "***[a] method for assessing toxicity of a test compound***, said method comprising: a) treating a biological sample containing nucleic acids with the test compound, b) hybridizing the nucleic acids of the treated biological sample ***with a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 52*** under conditions whereby a specific hybridization complex is formed between said probe and a target polynucleotide in the biological sample, ***said target polynucleotide comprising a polynucleotide sequence of a polynucleotide of claim 52***..." Such motivation simply does not exist.

Instead, the Examiner has chosen to ignore the claim recitations relating to a target polynucleotide of a polynucleotide of claim 52. It is well settled law that to establish a *prima facie* case of obviousness, **all the claim limitations must be taught or suggested by the prior art**. See, e.g., *In re Royka*, 180 USPQ 580 (CCPA 1974); and MPEP § 702.02(j) and § 2143.03. The probes recited by claims 54 and 66 must be used under appropriate conditions to allow for detection of the target polynucleotide (claim 54), or for formation of a specific hybridization complex between the probe and the target polynucleotide (claim 66). None of the cited art would guide one to such a method because none of those documents describe the polynucleotides of claim 52.

IV. CONCLUSION

For all of the foregoing reasons and the reasons stated in Appellants' Brief on Appeal, it is urged that the decision of the Examiner rejecting claims 45, 47-49, 52, 54-56 and 66-68, on appeal, is in error and should be reversed.

Appellants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

This brief is enclosed in triplicate.

Respectfully submitted,

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